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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,444	05/22/2002	Christian Von Falkenhausen	3868-0113 P	6939

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,444	FALKENHAUSEN ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/6/06 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of the Griffin et al (EP 0 010 987 hereafter '987) and Biegajski et al (USPN

5,700,478 hereafter '478). The claims are drawn to a controlled release preparation where the active agent is disposed onto a laminated sheet, and the sheet is rolled or folded.

2. The '987 reference discloses a rolled up preparation for the controlled release of active agent in the body (abstract). The laminate comprises an erodible layer, which contains the active agent, and a non-erodible layer (Figure 1). When the preparation is rolled the diameter greater than 0.5 mm (page 8, line 10-30). The device can be covered with equally erodible layers for delivery (page 6, line 28-34). The device is designs to open and assume a flat shape once in the stomach (abstract). The particular release profiles can be determined though routine experimentation and changed to fit the needs of the patient (page 5, line 1-14). The drug-containing layer is attached to a carrier, rolled, and delivered to the patient (examples). The device can further comprising water-soluble layers that help unfold the device (page 8, line 1-9). The reference is silent to the inclusion of a pressure-sensitive adhesive layer, though it is disclosed that some polymers in the laminate may be sticky and a water-soluble polymer such as rice paper or other water-soluble polymers should be used (page 8, line 1-9). The inclusion of a pressure-sensitive adhesive however would be obvious to an artisan of ordinary skill since they would want the unfolded patch to adhere to the delivering surface. These pressure sensitive adhesive polymers would be readily available and obvious to one of ordinary skill as seen in the '478 patent.

3. The '478 patent discloses a water-soluble pressure-sensitive adhesive that may constitute a part of a device that must be held at a particle point in the body (abstract). The adhesives are particularly useful in the construction of laminated devices for the controlled delivery of substances within a mucosa-lined environment (col. 3, lin. 45-50). The release can be

controlled by the structure of the device and can fit various dosing regimens (col. 4, lin. 1-20). The adhesive layers can dissolve once exposed to body fluids adding to the delivery options (col. 4, lin. 21-46). It would have been obvious to include the pressure sensitive adhesive layers of the '478 into the rolled device of the '987 in order to insure a preferred release and adherence to the specific application situs.

4. The references are silent to the inclusion of active agents in the water-insoluble layer. However, it is the position of the examiner that such a limitation lacks criticality barring a showing thereof. The device of the reference performs identically to that of the instant claims, and is within the same field of endeavor. Further the orientation of the drug-containing sheet can be determined by routine experimentation and by those of ordinary skill in the art. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

5. With these aspects in mind it would have been obvious to include the pressure sensitive adhesives of the '478 patent into the carriers of the rolled device of the '987 in order to provide a specific differential release of active agents and allow the device to adhere to the body internally insuring proper release of the active agents. It would have been obvious to combine the

teachings and suggestions of the art with an expected result of an adhesive patch capable of variable release rates.

Response to Arguments

6. Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection. However the Griffin patent discloses that some of the materials of the active agent layer may be sticky (adhesive). Due to this a water-soluble layer should be added that would erode once in the body such as rice paper. It remains the position of the Examine that the concentration of the active agent in relation to the structure of the device is not patentable over the art. The griffin patent teaches that the concentration can be changed based on the artisans desired release profile. Likewise the '478 patent discloses that the layer can be manipulated to release active agents in any desired controlled release fashion. Due to these disclosures the claims remain obviated.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER